UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler, District Court Judge

Honorable Karen M. Williams, Magistrate Judge

THE ZHP PARTIES' BRIEF IN SUPPORT OF THEIR MOTION FOR A PROTECTIVE ORDER PRECLUDING THE DEPOSITION OF ZHP PRESIDENT BAOHUA CHEN

TABLE OF CONTENTS

		<u>_</u>	Page
INTR	RODU	CTION	1
PERT	ΓINEN	T FACTUAL AND PROCEDURAL BACKGROUND	2
I.	THE	CHEN HAD NO MATERIAL INVOLVEMENT IN ANY OF KEY FUNCTIONS OF THE ZHP PARTIES AT ISSUE IN THIS GATION	2
II.	PERT	ΓINENT PROCEDURAL BACKGROUND	12
ARG	UMEN	NT	13
I.	THE	APEX DOCTRINE	14
II.	AGA	NTIFFS HAVE NOT REBUTTED THE PRESUMPTION INST MR. CHEN'S DEPOSITION UNDER THE APEX TRINE	16
	A.	Mr. Chen Is Not the Only Connection Between ZHP, Shanghai Syncores, Prinbury, Huahai US, Prinston, and Solco	17
	B.	Mr. Chen Does Not Possess Unique Knowledge as to the FDA	20
	C.	Mr. Chen Does Not Possess Unique or Superior Knowledge as to the Cost of Manufacturing	23
	D.	Mr. Chen Does Not Possess Unique Knowledge as to the Recall of Valsartan	26
	E.	Mr. Chen Was Not Involved in the Irbesartan Development Process or Plaintiffs' Fabricated Cover Up	27
III.	ADD	MOTION SHOULD BE HELD IN ABEYANCE UNTIL THE ITIONAL DISCOVERY PLAINTIFFS HAVE REQUESTED IS IPLETED	29
CON	CLUS	ION	30

TABLE OF AUTHORITIES

Federal Cases

Ciarrocchi v. Unum Grp., No. CV 08-1704, 2009 WL 10676631 (D.N.J. Aug. 27, 2009)	, 29
George v. Pennsylvania Tpk. Comm'n, No. 1:18-CV-766, 2020 WL 2745724 (M.D. Pa. May 27, 2020)	, 29
Pollock v. Energy Corp. of Am., No. CIV.A. 10-1553, 2015 WL 757458 (W.D. Pa. Feb. 23, 2015), aff'd, 665 F. App'x 212 (3d Cir. 2016)	, 29
United States ex rel. Galmines v. Novartis Pharm. Corp., No. CV 06-3213, 2015 WL 4973626 (E.D. Pa. Aug. 20, 2015)	, 28
Younes v. 7-Eleven, Inc., No. CV 13-3500 (RMB/JS), 2015 WL 12844446 (D.N.J. Aug. 19, 2015)	, 28
Rules	
Fed. R. Civ. P. 26	14
Fed. R. Civ. P. 26(b)(2)(C)	14
Fed. R. Civ. P. 26(c)(1)	14

INTRODUCTION

Plaintiffs have not and cannot overcome the presumption against the apex deposition of ZHP President Baohua Chen. Given the massive record of 17 depositions of ZHP Party witnesses, ten of whom have been designated as corporate representatives to testify on the 59 topics in Plaintiffs' 30(b)(6) notice of deposition, and more than 350,000 non-custodial documents and custodial files from 83 custodians who Plaintiffs themselves identified as having the information necessary to develop their case regarding the presence of nitrosamines in valsartan, the threshold for Plaintiffs' request for Mr. Chen's deposition is exceedingly high. Under the apex doctrine, Plaintiffs must articulate what this expansive record does not show about the material facts at issue that Mr. Chen's testimony, and only Mr. Chen's testimony, would provide. Plaintiffs' basis must be drawn from the record without speculation or fabrication.

The apex doctrine requires Plaintiffs to point to something in the expansive record of testimony and documents that demonstrates that Mr. Chen has some unique information as to how the nitrosamines occurred in valsartan or how they could have been avoided that could not have been obtained from, *inter alia*, (i) any of the 17 ZHP Party witnesses deposed, (ii) the 350,000 documents from 83 custodians and non-custodial files, or (iii) any of the other approximately 7,000 employees of the ZHP Parties whose depositions would be less burdensome than a deposition of Mr.

Chen. Plaintiffs have not satisfied – and cannot satisfy – this exceedingly high burden given Mr. Chen's role as President of the global organization that is ZHP. There is nothing in the record demonstrating, nor any reason to believe, that Mr. Chen has or could possess any unique knowledge about the material facts at issue in this litigation.

Accordingly, for these reasons, as discussed more fully below, the Court should grant the ZHP Parties' Motion for Protective Order and preclude a deposition of Mr. Chen under the apex doctrine.¹

PERTINENT FACTUAL AND PROCEDURAL BACKGROUND²

I. MR. CHEN HAD NO MATERIAL INVOLVEMENT IN ANY OF THE KEY FUNCTIONS OF THE ZHP PARTIES AT ISSUE IN THIS **LITIGATION**

As set forth in Sections II.A and II.B of the Opposition, Mr. Chen in his roles as ZHP's founder and President had no material involvement in the valsartan manufacturing, testing, analytical, quality control, quality assurance, research and development, recall, regulatory and sales functions at issue in this litigation. See Dkt.

¹ As discussed at Section III *infra*, the Court should hold this motion in abeyance until the additional discovery Plaintiffs have requested is completed.

² The ZHP Parties incorporate by reference their Opposition Brief to the Motion to Compel Mr. Chen's Custodial File and Cross Motion for Productive Order ("Opposition"), Dkt. 1244. To avoid repetition, the ZHP Parties cross-reference the Opposition herein.

1244 at 3-6. The following record facts further demonstrate that Mr. Chen cannot provide any material information beyond the expansive discovery submitted to date.

Following the service of Plaintiffs virtually identical 30(b)(6) notices on each of the four ZHP Parties on December 2, 2020 (see Dkt. 651-1), the ZHP Parties designated ten witnesses to testify as to 59 different 30(b)(6) topics, see Dkt. 703-1, including nine ZHP Party department heads and lower-level employees at each of the ZHP Party entities implicated by Plaintiffs' allegations about valsartan. The designated representatives are the individuals who implemented the valsartan manufacturing, testing, analytical, quality control, quality assurance, research and development, recall, and regulatory functions at issue. The corporate designees also provided testimony in their individual capacity, along with seven other ZHP Party witnesses noticed for depositions in their individual capacity. In total, at the conclusion of this portion of fact discovery on May 31, 2021, Plaintiffs will have conducted 17 ZHP Party depositions. To date, Plaintiffs have completed nine 30(b)(6) depositions and four individual depositions, and taken 136.5 hours of deposition testimony.

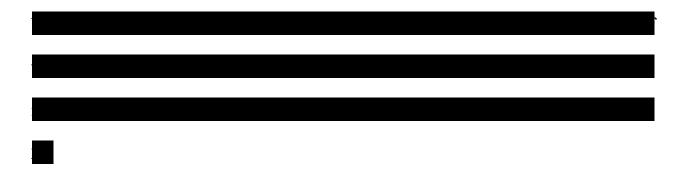
The employees deposed were consistent and unequivocal that Mr. Chen was not involved in the highly technical API manufacturing issues at the center of this

case. See Exhibit A.3 Rather, as the head of ZHP since founding it in 1989, Mr. Chen's role has always been managerial. The employees deposed, as described more fully below, have been available to testify (and have testified extensively) about every material fact at issue in this case:

Eric Gu, President of Shanghai Syncores Technologies, Inc.

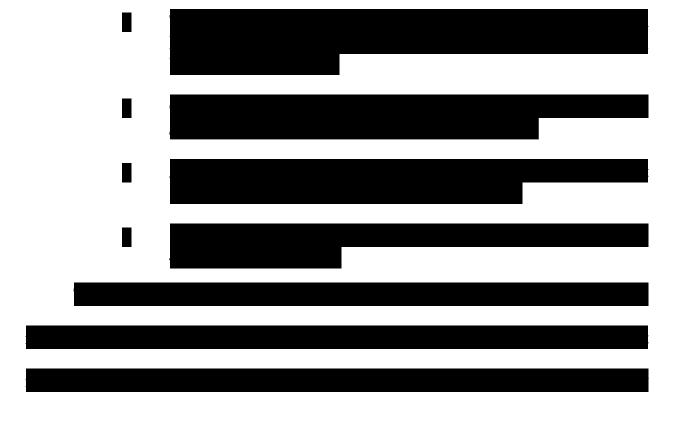
Eric Gu, the President of Shanghai Syncores Technologies, Inc. ("Shanghai Syncores"), was designated to testify on two 30(b)(6) topics involving process development. During his deposition, Mr. Gu thoroughly testified about the See Exhibit C, Eric Gu Tr. at 60:6-60:10; 94:3-94:12; 114:10-114:17; 133:17-134:21.

³ As set forth in the Opposition, the sheer and indisputable absence of any documents tying Mr. Chen to any fact or issue of import in this case in the more than 350,000 documents produced from over 83 ZHP Party custodians, as well as non-custodial documents, based on more than 400 search terms, corroborates the testimony that Mr. Chen has no material involvement in any such fact or issue. See Opposition, Dkt. 1244 at 6-8. Indeed, Mr. Chen is mentioned in just 13 documents admitted as deposition exhibits, all of which also identified the witnesses whom Plaintiffs questioned about the document. See Exhibit B.



Hai Wang, President of Solco Healthcare U.S., LLC

Hai Wang, President of Solco Healthcare U.S., LLC, was designated to speak to 17 30(b)(6) topics including ZHP's communications with API and finished dose customers and downstream customers, product tracing, and testing of valsartan API. Mr. Wang extensively testified to the all of these topics (including others) and Plaintiffs had the full opportunity to ask Mr. Wang questions with regards to:



Minli Zhang, Director of Finished Dose Formulation Quality at Zhejiang Huahai Pharmaceutical Co., Ltd.

Designated to cover 20 30(b)(6) topics, including the testing of valsartan finished dose products, quality assurance and quality control activities at the finished dose manufacturing site, and compliance with current good manufacturing practices ("cGMPs"), Minli Zhang, Director of Finished Dose Formulation Quality at ZHP, comprehensively covered these topics. In particular, she provided fulsome testimony to questions posed by Plaintiffs regarding these topics, among others:

Peng Dong, Deputy Director of Technology at Zhejiang Huahai Pharmaceutical Co., Ltd.

Peng Dong, the Deputy Director of Technology at ZHP, was designated to testify to *five 30(b)(6) topics* including the testing of valsartan API and process development. Specifically, Peng Dong testified to the

See Exhibit F,

Page 10 of 33

Peng Dong Tr. at 86:17-86:24; 203:16-204:3. Additionally, Mr. Peng answered questions posed by Plaintiffs regarding, among other topics:



• Qiangming Li, Director of Analysis at Zhejiang Huahai Pharmaceutical Co., Ltd.

Designated to cover *nine 30(b)(6) topics*, Qiangming Li, the Director of Analysis at ZHP, testified

Mr. Li also answered questions regarding, among other topics:

PageID: 28781

• Min Li, Ph.D., Vice President of Analytical Operation at Zhejiang Huahai Pharmaceutical Co, Ltd.

Min Li, Ph.D., Vice President of Analytical Operation at ZHP, was designated to speak to *four 30(b)(6) topics* and provided specific testimony to Plaintiffs' questions regarding



• Jucai Ge, Director of API Quality Assurance at Zhejiang Huahai Pharmaceutical Co., Ltd.

Designated to testify to twelve 30(b)(6) topics, Jucai Ge, the Director of API Quality Assurance at ZHP, covered Specifically, at her deposition, In her deposition, Ms. Ge further explained that

Linda Lin, Director of Regulatory Affairs at Zhejiang Huahai Pharmaceutical Co., Ltd.

Document 1247-2

PageID: 28783

Linda Lin, the Director of Regulatory Affairs at ZHP since November 2016 and the Director of Regulatory Affairs for ZHP's API division prior to that, was designated to testify on *four 30(b)(6) topics* involving ZHP's communications with regulatory agencies. Ms. Lin has "been present at every FDA inspection of ZHP's facilities since 2004," and has "served as the primary FDA liaison for ZHP" for "all of th[os]e inspections[,]" demonstrating that she is unquestionably the person most knowledgeable about ZHP's interactions with the FDA. See Exhibit J, Decl. of Linda Lin, \P 7-8 (emphasis added).

Indeed, Ms. Lin thoroughly testified to

Moreover, the Regulatory Affairs Department, not Mr. Chen, "are responsible for coordinating all communications with the FDA." Ex. J, ¶ 6. Mr. Chen is "not involved in drafting or compiling such communications" and only "participate[s] in the welcome and final meeting with the FDA." *Id.* at ¶¶ 6-9. Mr. Chen is listed as the "most responsible person" on some FDA reports only because "he was the highest level person present at ZHP's facilities at the time of the FDA inspection

Page 14 of 33

that is the subject of the report." Id. at ¶¶ 6, 9-11. However, Ms. Lin and subject matter experts at ZHP attend the inspections to provide information to the FDA about the specific aspects of the manufacturing site that are being inspected. Id. at ¶¶ 7, 10.

• Lijie Wang, Ph.D., Vice President of Regulatory Affairs at Prinston Pharmaceutical Inc.

Lijie Wang, Ph.D., Vice President of Regulatory Affairs at Prinston, was designated to testify to seven 30(b)(6) topics involving

• Jun Du, Vice President at Zhejiang Huahai Pharmaceutical Co., Ltd., and CEO of Huahai U.S., Inc., Prinston Pharmaceuticals Inc., and Solco Healthcare U.S.

Jun Du, Vice President at ZHP and CEO of Huahai U.S., Prinston, and Solco, will be deposed on May 27, 2021, and May 28, 2021 as an individual fact witness, not as a 30(b)(6) witness. Dkt. 1163. As explained more fully below, Jun Du is familiar with ZHP's U.S. entities and a number of the documents cited by Plaintiffs

in their December 21, 2020 letter requesting Mr. Chen's deposition also reference Jun Du. *See* Dkt. 685. As directed by the Court, the ZHP Parties will incorporate Mr. Du's deposition testimony in their supplemental briefing to this motion for protective order. *See* 5-3-21 Hrg. Tr. at 45:6-9.

• Jay (Jie) Wang, Vice President of Business Development at Zhejiang Huahai Pharmaceutical Co., Ltd.

Designated to testify on *seven 30(b)(6) topics*, Jie Wang, Vice President of Business Development at ZHP, will testify on May 17-18, 2021, regarding:

- O Communications with API and finished dose customers and downstream customers (Topics 42 and 43);
- Credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP (Topic 47); and
- O Product tracing and pricing and sales of valsartan API and valsartan finished dose ultimately sold in the United States (Topics 50, 52, 54, 56, and 58).

As with Mr. Du, the ZHP Parties will incorporate Mr. Wang's testimony in their supplemental briefing to this motion for protective order.

II. PERTINENT PROCEDURAL BACKGROUND

Although Judge Schneider ordered the ZHP Parties to provide a date for Mr. Chen's deposition in December 2020, he explicitly acknowledged that Mr. Chen's deposition might be unnecessary depending upon the deposition testimony of the other 17 ZHP Party witnesses. Hrg. Tr. 12-22-20 at 41:7-10 (THE COURT: "[I]f other depositions are taken, you might have a better record to show, in fact, that this

testimony is, in fact, duplicative, cumulative, or nonmaterial," and "after a sufficient deposition record is developed, ZHP is granted leave to file a Motion for Protective Order to quash Mr. Chen's deposition."); Hrg. Tr. 1-05-21 at 26:1-5 (THE COURT: "If it turns out that the depositions are not ordered, then they can be taken off the schedule; but to make sure there's no lag or undue delay, ZHP will be ordered to give proposed tentative dates for these witnesses' depositions as well as Mr. Chen."); see also Dkt. 704. On May 3, 2021, this Court granted the ZHP Parties' request to file the instant motion for a protective order to preclude Mr. Chen's deposition under the "apex" doctrine. Dkt. 1217.

Document 1247-2

PageID: 28786

ARGUMENT

As demonstrated below, not one of the bases for Plaintiffs' request for the deposition of Mr. Chen is sufficient to rebut the presumption against his deposition as an apex witness.⁴ Instead, the testimony of 13 ZHP Party witnesses (to date) and the more than 350,000 documents produced clearly establish that (1) Mr. Chen does not have personal or superior unique knowledge of the facts alleged; and (2) the information sought has been and continues to be obtained through a less intrusive method by deposing lower level employees. Accordingly, the Court should grant the

and demonstrated that not one of those arguments connects Mr. Chen to the material issues of this litigation. See Opposition, Dkt. 1244, at 13-18.

⁴ Some of these arguments, and additional arguments, were identified by Plaintiffs in seeking Mr. Chen's custodial file. The ZHP Parties have refuted those arguments

Case 1:19-md-02875-RMB-SAK

PageID: 28787

ZHP Parties' Motion for Protective Order and preclude the deposition of Mr. Chen. Plaintiffs simply have not and cannot point to a single fact in the record to show, without speculation or fabrication, that Mr. Chen has information about the material facts at issue that no other employee among the approximately 7,000 at the ZHP Parties, including the *17 deponents*, has provided or could provide.

I. THE APEX DOCTRINE

Under Rule 26 of the Federal Rules of Civil Procedure, district courts must issue protective orders to protect parties and entities from "annoyance, embarrassment, oppression, or undue burden or expense[.]" Fed. R. Civ. P. 26(c)(1) (emphasis added). Courts "must limit the frequency or extent of discovery" if "the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive[.]" Fed. R. Civ. P. 26(b)(2)(C).

Applying these principles, courts have developed the "apex doctrine" to limit depositions of individuals at the "apex" of corporations, which are presumed likely to be duplicative and unduly burdensome. *United States ex rel. Galmines v. Novartis Pharm. Corp.*, No. CV 06-3213, 2015 WL 4973626, at *1 (E.D. Pa. Aug. 20, 2015). Indeed, depositions of high-level officers impose a heavy burden on those officers and the entities they represent, and "adversaries might use this severe burden to their

unfair advantage." *Id*. Courts "presum[e] that a high-level official's deposition *represents a significant burden*[.]" *Id*. at *2 (emphasis added).

To rebut that presumption, a party must establish that (1) "the executive or top-level employee has personal or unique knowledge on relevant subject matters;" and (2) the information sought cannot "be obtained from lower-level employees or through less burdensome means[.]" *Younes v. 7-Eleven, Inc.*, No. CV 13-3500 (RMB/JS), 2015 WL 12844446, at *2 (D.N.J. Aug. 19, 2015) (quotations omitted).

If an apex witness lacks unique knowledge, the witness shall not be deposed. Ciarrocchi v. Unum Grp., No. CV 08-1704 (JBS/AMD), 2009 WL 10676631, at *3 (D.N.J. Aug. 27, 2009) (prohibiting apex deposition because plaintiff failed to show that witness had unique knowledge); George v. Pennsylvania Tpk. Comm'n, No. 1:18-CV-766, 2020 WL 2745724, at *3 (M.D. Pa. May 27, 2020) (denying motion to compel apex deposition, notwithstanding fact that he participated in events at issue, because "it cannot be said that he possessed superior, or unique knowledge of these events"). And apex witnesses often do not possess any unique knowledge when there already has been a "mountain of discovery taken in the case." Younes, 2015 WL 12844446, at *2.

Courts have found that an apex witness does not possess unique knowledge merely because he or she (1) holds an important position or title in the company, *see*, *e.g.*, *United States ex rel. Galmines*, 2015 WL 4973626, at *1-3 (quashing subpoena

for apex deposition where opposing party had already "deposed six corporate representatives ... and 12 fact witnesses"), (2) "sign[s] off on some paperwork[,]" see, e.g., Younes, 2015 WL 12844446, at *2, or (3) is a custodian of documents, see id. at *3.

Even if an apex witness possesses certain information, courts prohibit apex depositions where the information could be obtained from other available witnesses. *See id.* at *2; *Ciarrocchi*, 2009 WL 10676631, at *3. Thus, *when a plaintiff has the opportunity to depose multiple corporate designees, apex depositions are inappropriate. See George*, 2020 WL 2745724, at *3 (denying motion to compel apex deposition because lower-level corporate designees were deposed on the topics); *Pollock v. Energy Corp. of Am.*, No. CIV.A. 10-1553, 2015 WL 757458, at *6 (W.D. Pa. Feb. 23, 2015), *aff'd*, 665 F. App'x 212 (3d Cir. 2016) (prohibiting apex depositions because plaintiffs already deposed the company's vice president of accounting and vice president of marketing).

II. PLAINTIFFS HAVE NOT REBUTTED THE PRESUMPTION AGAINST MR. CHEN'S DEPOSITION UNDER THE APEX DOCTRINE

As demonstrated by the 59 topics in Plaintiffs' 30(b)(6) notice, this case concerns the manufacturing, testing, quality, research and development and regulatory functions pertaining to the alleged impurities in valsartan. Plaintiffs' original request for Mr. Chen's deposition in December 2020, *see* Dkt. 685, rests on

a handful of documents they claim demonstrate
The massive record of documents and testimony, including 13 ZHP Par
witnesses already deposed, ⁵ demonstrates that none of those documents warrants M
Chen's deposition under the apex doctrine.
A. Mr. Chen Is Not the Only Connection Between ZHP, Shanghand Syncores, Prinbury, Huahai US, Prinston, and Solco
See cases cited supra.

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⁵ The Court has already granted the ZHP Parties leave to file a supplement this brief with the testimony of Jun Du. The ZHP Parties will also include the testimony of Jie Wang, Karen Xu, and Xiaodi Guo, who will be deposed during the week immediately following the filing of this brief on May 17, 2021. *See* 5-3-21 Hrg. Tr. at 45:6-9.

	Furthermore	e, multiple	additional	witnesses	can	speak	to t	he r	elationship
betwo	een a number	of the ZHI	entities.						

⁶ The fact that Mr. Chen visits ZHP's U.S. subsidiaries does nothing to show he has unique or superior knowledge of any of the material issues in this case. *See also* Opposition, <u>Dkt. 1244</u> at 14.

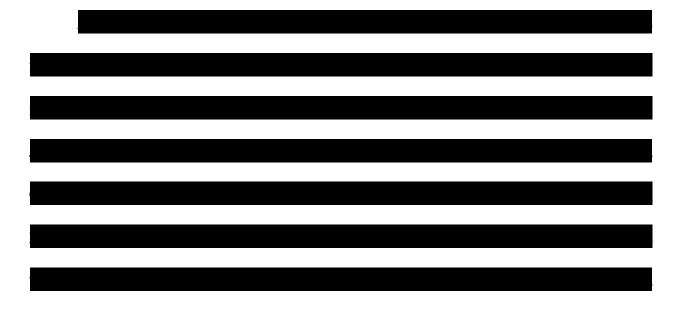
In short, Plaintiffs have deposed or will have the opportunity to depose a number of witnesses that understand the relationships between different ZHP entities. To the extent Mr. Chen even has an understanding of the relationship between the ZHP entities, that information would unquestionably be duplicative and cumulative.

Notwithstanding the blatant falsity of Plaintiffs' assertion that Mr. Chen is the
only person who ties all of the entities and departments together, the assertion is stil
not sufficient to overcome the presumption against apex depositions.

Accordingly, Mr. Chen simply does not possess unique knowledge of th
relationship between ZHP Party entities or their departments.
B. Mr. Chen Does Not Possess Unique Knowledge as to the FDA
Indeed, FDA communications, filings, and disclosures wer
included in <i>at least 10 30(b)(6) topics</i> . See <u>Dkt. 703-1</u> , at 6.

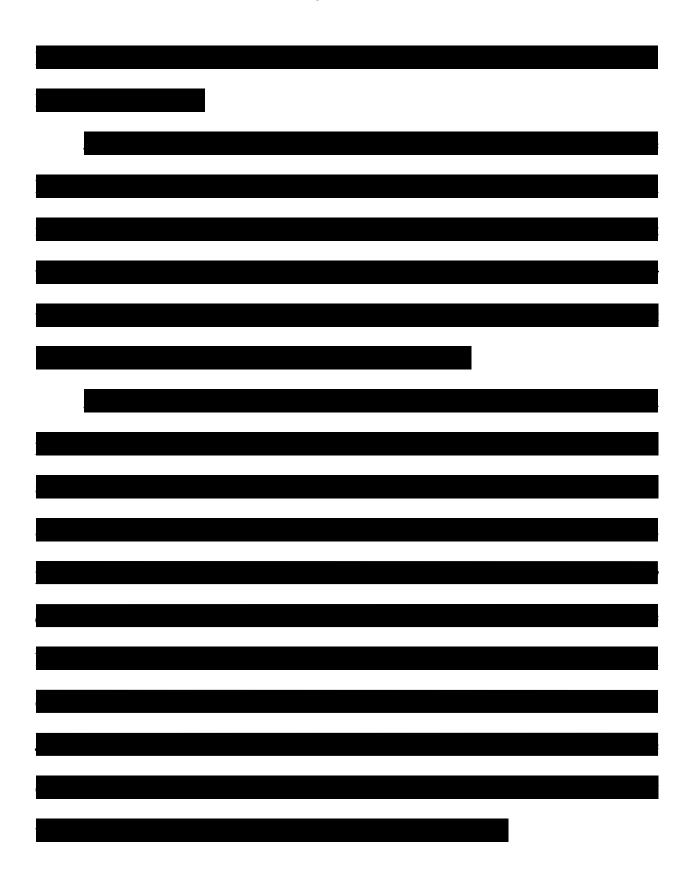


Moreover, Plaintiffs fail to mention the other ZHP employees who participated in the FDA inspections. "The Opening Meeting Attendants" list in the June 5, 2017 FDA inspection report lists Jie Wang, Linda Lin, Minli Zhang, and Xiaodi Guo – all of whom Plaintiffs either have deposed or will have the opportunity to depose. Exhibit P; ZHP00005780.8



⁷ See also Opposition, <u>Dkt. 1244</u> at 15-16.

⁸ The report lists nine custodians whose files have already been produced. *See also* Opposition, <u>Dkt. 1244</u> at 16.



In short, Plaintiffs have had the opportunity to ask any of these seven witnesses—Linda Lin, Min Li, Xiaodi Guo, Minli Zhang, Eric Tsai, Remonda Gergis, and Jun Du—about FDA inspections. Accordingly, the information sought can be obtained through lower level employees and not Mr. Chen.

С.	Mr. Chen Does Not Possess Unique or Superior Knowledge as to the Cost of Manufacturing



Plaintiffs also cannot refute that other corporate designee witnesses have or could have testified about this topic. Indeed, *at least seven ZHP Party witnesses* have addressed it:



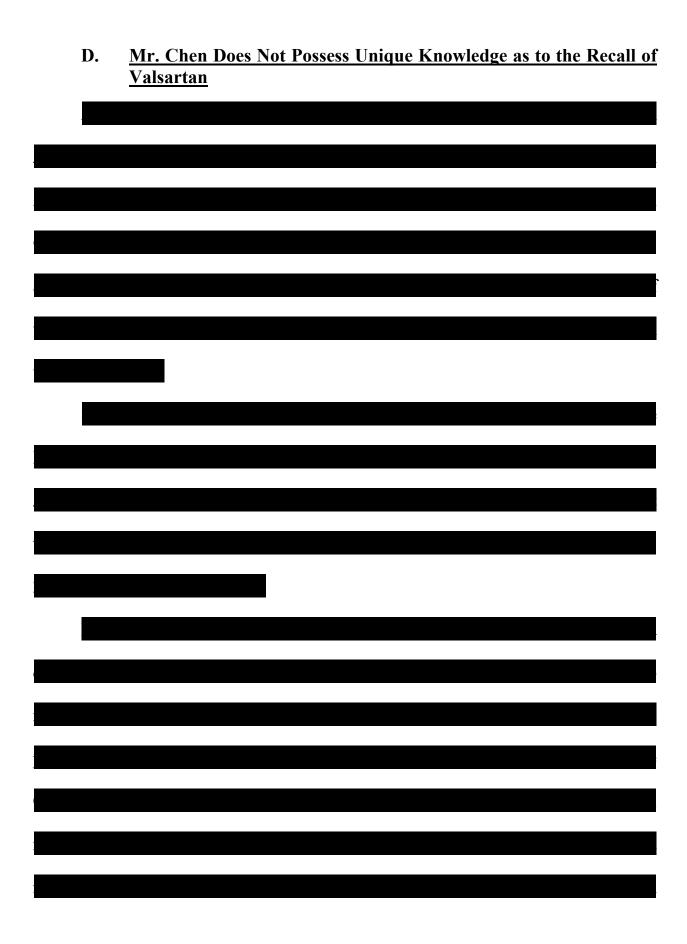
⁹ Shanghai Syncores is located in Shanghai, a four to five hour car trip from ZHP's headquarters, where Mr. Chen is based.

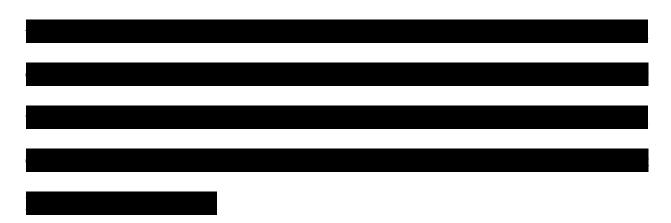


Accordingly, Eric Gu, Peng Dong, Min Li, Hai Wang, Minli Zhang, Jucai Ge, Linda Lin, and Jun Du have knowledge as to these topics, and testimony from Mr. Chen is not necessary nor justifiable under the apex doctrine. 11

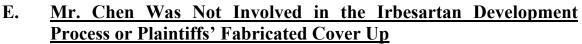


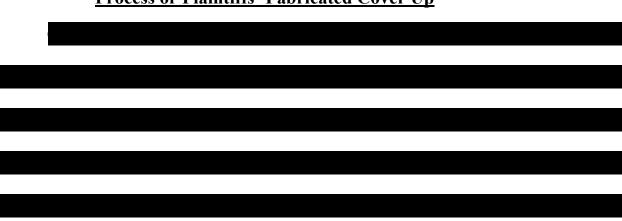
¹¹ See also Opposition, <u>Dkt. 1244</u> at 16-17.





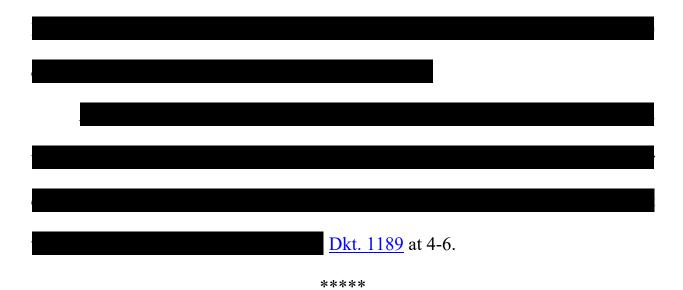
Accordingly, Plaintiffs have not (and cannot) identify any unique knowledge Mr. Chen has regarding the recall of valsartan that other members of the recall group would not also have.¹²



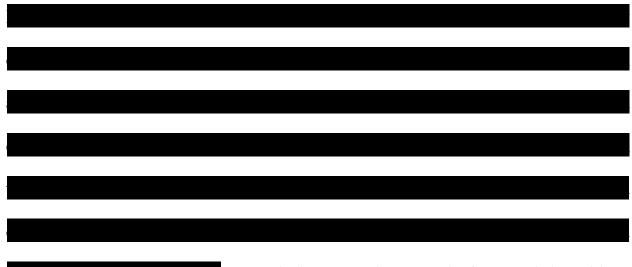


¹² *See also* Opposition, <u>Dkt. 1244</u> at 13-14.





As demonstrated above, Plaintiffs have not rebutted the presumption against Mr. Chen's deposition under the apex doctrine sufficient to compel his deposition.



Instead, the expansive record of 17 total depositions and more than 350,000 documents produced is sufficient to provide Plaintiffs with all material information they might need in support of their claims. *See United States ex rel. Galmines*, 2015 WL 4973626, at *1-3; *Younes*, 2015 WL 12844446, at *2;

Ciarrocchi, 2009 WL 10676631, at *3; *George*, 2020 WL 2745724, at *3; *Pollock*, 2015 WL 757458, at *6.

Testimony by Mr. Chen would not add any unique information to that record, and accordingly, under the apex doctrine, the Court should preclude his deposition.

III. THIS MOTION SHOULD BE HELD IN ABEYANCE UNTIL THE ADDITIONAL DISCOVERY PLAINTIFFS HAVE REQUESTED IS COMPLETED

On April 27, 2020, Plaintiffs requested the production of Mr. Chen's custodial file and additional discovery pertaining to the email discussed above regarding To debunk Plaintiffs' fabricated claim of a cover-up, the ZHP Parties have agreed to provide virtually all of the additional discovery Plaintiffs have requested relating to that email, including:

- Producing the custodial files of *seven* additional custodians based on the original 400+ search terms;
- Reviewing the collection of *thirteen* custodians and, if necessary, supplementing their production with any additional responsive, non-privileged documents; and
- Applying the following *six new search terms* across all existing and new custodians and producing any additional responsive, non-privileged documents:

See <u>Dkt. 1228</u>.

Although the ZHP Parties are confident that nothing in Mr. Chen's custodial file (were it ordered to be produced) or the additional discovery the ZHP Parties have

PageID: 28803

agreed to provide would rebut the presumption against Mr. Chen's deposition, Plaintiffs are, nonetheless, likely to argue otherwise. Accordingly, given the presumed burden of deposing an apex witness like Mr. Chen, and the principle that an apex deposition should only be decided based on a fully developed discovery record, the Court should hold this motion in abeyance until the additional discovery Plaintiffs have requested is completed.

CONCLUSION

WHEREFORE, for all of the foregoing reasons, and those stated in the Opposition incorporated by reference herein, the ZHP Parties respectfully request that the Court grant its motion for protective order or hold the motion in abeyance until the additional discovery Plaintiffs have requested is completed.

May 17, 2021

Respectfully submitted,

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